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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,182

09/17/2003

Yasuhiro Katsu

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12/23/2004

EXAMINER

HUANG, EVELYN MEI

PFIZER INC.

PATENT DEPARTMENT, MS8260-1611

EASTERN POINT ROAD

GROTON, CT 06340

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,182	KATSU ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 and 31 is/are allowed.
- 6) ☒ Claim(s) 15-28, 32-35 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 15-35 are pending. Claims 1-14 have been canceled according to the amendment filed on 10-5-2004.

Duplicate Claims

2. The cancellation of Claim 2 has rendered moot the objection to its being a substantial duplicate of claim 1.

Claim Objections

3. The cancellation of Claims 8, 9 has rendered moot the objection under 37 CFR 1.75(c) to their being in improper form.

Claim Rejections - 35 USC § 112

4. The cancellation of Claims 1-9, 12-14 has rendered moot the 112 second paragraph rejection.

Claim Rejections - 35 USC § 112(1)

5. The rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for claim 13 is rendered moot by its cancellation. However, new claims 34-35 are subjected to the written description rejection for the following reasons.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A full description of the inventive compound as agonists and/or antagonists of the 5-HT₄ receptors is not found in the specification. The instant method for agonizing 5-HT₄ receptors or antagonizing the 5-HT₄

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receptors reaches out to as yet unidentified diseases/conditions/activities, the description of which is not found in the specification.

Claim Rejections - 35 USC § 112(1)

6. The rejection for Claims 1-9, 12-14 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is rendered moot by the cancellation of these claims. However, new claims 34-35 are subjected to the enablement rejection for the following reasons.

Biological pathways by themselves are devoid of identifiable utility and are therefore not useful. Unless the pathway at issue is critical to treating some condition and the pathway modification and disease treatment are inexorably linked, such pathway modification is devoid of utility. The instant claim directed to a mechanism of agonizing or antagonizing 5-HT4 receptors without the end result would therefore have no practical utility unless the agonism or antagonism of 5-HT4 receptors and treatment of diseases are inexorably linked.

At the time of the invention, a nexus between the activation or inhibition of 5-HT4 receptors and the treatment or prevention of any or all of the recited diseases have not been fully established (Barnes et al. Neuropharmacology 38(1999) 1083-1185, 1118-1125). Furthermore, since the claims as recited embrace any degree of agonizing or antagonizing 5-HT4 receptors, which may or may not inexorably linked to the treatment of any or all the diseases recited, the scope of the claims therefore does not commensurate with that of the objective enablement, especially in view of the absence of a full written description of the as yet unidentified conditions/activities/disorders which the recited mechanism reaches out to. One of ordinary skill in the art therefore would not be able to use the inventive compound as claimed without undue experimentation.

Claim Rejections - 35 USC § 112(2)

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 15-28, 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 15, definition of R3, 'heterocyclic or heterocycliccarbonyl containing 1 to 4' is incomplete.
- b. Claims 27-28, for the 'heterocycliccarbonyl containing 1 to 3 heteratoms', does the oxygen of the carbonyl included in the 1 to 3 heteratoms?
- b. Claims 32-33, it is unclear whether these are compound claims or composition claims. Rewriting the claims in the proper format for the composition claim or compound claim is recommended.
- c. For the method claims 34-35, the amount of the compound administered to the mammalian subject is missing but required.

The rejection is applicable to claims dependent on the above claims.

Allowable Subject Matter

8. Claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

claims 30, 31 are allowed.

Uchida (6624162) discloses a 5 HT4 receptor binding piperidinyl-imidazopyridine compound similar to the instant. Uchida's piperidinyl is substituted by hydrogen, alkyl or alkoxyalkyl, whereas the alkyl on the piperidinyl in the instant compound is required to be substituted by one or two substituents not taught by Uchida. Absent is the motivation to modify the prior art compound to arrive at the instant invention.

Conclusion


9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625